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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,729	05/30/2001	Anthony P. Shuber	EXT-010CN	9406

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EXAMINER

TUNG, JOYCE

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 05/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/870,729

Applicant(s)

SHUBER, ANTHONY P.

Examiner

Joyce Tung

Art Unit

1637

**FILE**

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 May 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*.

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### **DETAILED ACTION**

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1637.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2 and 8-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claim 2 is vague and indefinite because of the language "said second portion is not complementary to any contiguous nucleic acid". It is unclear what is meant by "any contiguous nucleic acid" in the phrase. Clarification is required.

- b. Claims 8-15 are vague and indefinite because of the language "substantially complementary to said contamination detection sequence". It is unclear what is the metes and bounds for the language since the method is for the detection of contamination, the complementarity to said contamination detection sequence might be critical to the invention to avoid false position results. Clarification is required.

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- c. Claims 8-15 are vague and indefinite because it is unclear what is the definition of "contamination detection sequence". Clarification is required.
3. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: it is unclear how the amplicon is produced and how the amplicon is related to the detection of contamination.

#### ***Drawings***

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims since the second nucleic acid amplification step was not shown on the drawings. Therefore, the subject matter must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

#### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Shuldiner et al. disclose a method of detecting an RNA sequence, in the first step, a first oligonucleotide primer designated d<sub>20</sub>-t<sub>21</sub> comprises the 3' end, a nucleotide sequence complementary to the 3' end of the RNA and the 5' end, a unique random nucleotide sequence or

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tag which does not hybridize to the RNA sequence within the sample. The primer is extended (See pg. 7, lines 9-24). The resulting DNA segment is tagged with the unique 5' sequence ( $T_{21}$ ). This teachings anticipate the description of the first nucleic acid primer and the first reaction as claimed in claim 1.

In the second step, primer  $U_{21}$  and  $T_{21}$  are used in which primer  $U_{21}$  comprises the sequence complementary to the single stranded DNA segment produced in step 1 and primer  $T_{21}$  comprises the unique nucleotide sequence (See pg. 8, lines 11-28). Primer  $U_{21}$  is extended (See pg. 9, lines 1-4) and primer  $T_{21}$  is extended in second PCR cycle by hybridizing to the unique 5' sequence ( $T_{21}$ ) (See pg. 9, lines 6-7). This distinguishes between DNA generated from the RNA-template and possible contaminating DNA (See pg. 7, lines 27-29). Total RNA is from *Xenopus* pancreatic tissue (See pg. 14, lines 11-12). Thus, the teachings of Shuldiner et al. anticipate the limitations of claims 1-4, and 7.

As to claim 8, the language "a 5' contamination detection sequence" is unclear how it is defined. Accordingly, based upon the teaching of Shuldiner et al. as set forth above, the teachings of Shuldiner et al. anticipate the limitations of claims 8, and the dependent claims 10-11 and 13-15.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 5 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shuldiner et al. (WO 91/15601) as applied to claims 1-4, 7-8, 10-11 and 13-15 above, and further in view of Mullis et al. (4,965,188).

The teachings of Shuldiner et al. are set forth in section 6 above and Shuldiner et al. do not disclose the limitations of claims 5 and 12 that the detection is done with sequence specific nucleic acid probe capture and the sample is from stool.

Mullis et al. disclose that a process for amplifying any target nucleic acid sequence in a nucleic acid mixture (See the Abstract) and a sequence specific probe capture for detection (See column 5, lines 9-12).

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One of ordinary skill in the art at the time of the instant invention would have been motivate to combine the teachings of Shuldiner et al. and Mullis et al. with a reasonable expectation of success to make the instant invention because Mullis et al. disclose that PCR is used to amplify a desired nucleic acid sequence (See the Abstract) and the detection of the nucleic acid sequence is done with a probe (See column 5, lines 8-12). It would have been prima facie obvious to carry out the method as claimed.

9. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1656 via the PTO Fax Center located in Crystal

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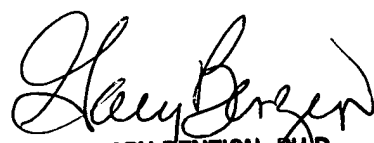
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Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

May 3, 2002

  
GARY BENZION, PH.D  
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